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10/718,683	11/24/2003	Francis Pruche	05725.1256-00	3211
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER				
VENKAT, JYOTHSNA A				
ART UNIT		PAPER NUMBER		
1615				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/718,683

**Applicant(s)**

PRUCHE ET AL.

**Examiner**

JYOTHSNA A. VENKAT

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55, 66, 68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55, 66 and 68-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of remarks, certified foreign translated document, IDS and remarks filed on 3/11/108. Receipt is also acknowledged of English translation of provisional application.

Applicant's are notified that the certified translation of provisional application and certified foreign translated document does not identify the application numbers either for provisional or foreign priority document on the first page. Explanation is requested with respect to the above translated documents not identifying the application numbers.

Claims 1-57, 66 and 68-69 are pending in the application.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-57, 66 and 68-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is written description rejection.**

*All the claims are rejected since there is no description in the specification for the species in claim 19 belonging to dye precursor "chosen from compounds comprising at least one aromatic ring comprising at least two hydroxyl groups borne by two successive carbon atoms of the at least one aromatic ring".*

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. *Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he

or she was in possession of the invention. The invention, for purposes of the “written description” inquiry, is “*whatever is now claimed*” (see page 1117).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states “An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention”. Hence, an adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus drawn to “all the derivatives recited in claim 19 for the dye precursors. There is no description for

derivatives of “3, 4-dihydroxyphenylalanine derivatives thereof, 2, 3-dihydroxyphenylalanine derivatives thereof, 4, 5-dihydroxyphenylalanine derivatives thereof, 4, 5-dihydroxyindole derivatives thereof, 5, 6-dihydroxyindole derivatives thereof, 6, 7-dihydroxyindole derivatives thereof, and 2, 3-dihydroxyindole derivatives thereof”.

The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention. *Lockwood v. American Airline, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli* 872 F.2d 1008,1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“ [T] he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus an applicant complies with written description requirement “ by describing the invention, with all its claimed limitation, not that which makes it obvious,” and by using “ such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood v. American Airline, Inc.*, 107 F.3d at 1572, 41 USPQ2d at 1966; *Regents of the University of California v. Eli Lilly &Co.*, 43 USPQ2d 1398.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder* 736 F.2d 1516, 1521, 222 USPQ 369, 372-373 (Fed. Cir. 1984) . Accordingly, it is deemed that the specification fails to provide adequate written description for the genus “ derivatives ” belonging to dye precursors recited in all the independent claims and does not reasonably

convey to one skilled in the relevant art the inventor(s), at the time the application was filed has possession of the entire scope of the invention.

***Response to Arguments***

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

Applicants' argue that there is literal support for "derivatives" at paragraph 51 of the specification and one skilled in the art would certainly recognize that applicants' were in possession of the genus drawn to "all the derivatives recited in claim 19 for the dye precursors". Applicants also argue that in the present application, applicants have provided structural description of a number of species falling within the scope of the genus of dye precursors recited in the claims.

In response, the specification at paragraph states the derivatives claimed in claim 19 for dye precursors without describing the specific compounds under derivatives. See below for dye precursors which recite "derivatives thereof".

**3,4-dihydroxyphenylalanine and derivatives thereof;**

- 2,3-dihydroxyphenylalanine and derivatives thereof;
- 4,5-dihydroxyphenylalanine and derivatives thereof;
- 4,5-dihydroxyindole and derivatives thereof;
- 5,6-dihydroxyindole and derivatives thereof;
- 6,7-dihydroxyindole and derivatives thereof;
- 2,3-dihydroxyindole and derivatives thereof;

Specification fails to describe the compounds for "phenyl alanine derivatives". A derivative is obtained by derivatizing the functional group present in the moiety. Phenylalanine derivatives are obtained by converting the hydroxy group or converting the amino group under di hydroxy phenyl alanine compounds. Specification does not describe one species by describing the compound in which the derivative is obtained by converting the hydroxy moiety (one or both) into another compound or converting the amino functionality in alanine into another compound. The same is true for indole derivatives. Indole derivatives are obtained by converting the hydroxy group or quaternizing the NH group in the indole skeleton. Specification neither names the compounds for derivatives nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds and therefore the specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention drawn to species in claim 19 belonging to dye precursor "chosen from compounds comprising at least one aromatic ring comprising at least two hydroxyl groups borne by two successive carbon atoms of the at least one aromatic ring".

Claims 3-11, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no charge for  $\text{HCO}_3^-$ . Bicarbonate is an anion and it has negative charge.

The expression "derivatives thereof (at all occurrences) is without metes and bounds. Recourse to the specification does not define these compounds.

***Response to Arguments***

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

**Applicants' argument**

"The Examiner asserts that claims 3-11 are indefinite because "there is no charge for [HCO<sub>3</sub>]" recited in these claims. See *id.* Applicants respectfully disagree. As the Examiner points out, one of ordinary skill in the art would understand that bicarbonate is an anion resulting from the deprotonation of carbonic acid, H<sub>2</sub>CO<sub>3</sub>. See Office Action, at page 7. Indeed, the U.S. Patent Office has previously found the notation [HCO<sub>3</sub>] to be allowable. See claim 1 of U.S. Patent No. 6,953,486 to Pruche ("Pruche"). The Examiner even cites Pruche in a § 103 rejection against the claims of the present application, thus the Examiner, who is arguably one skilled in the art, understood the meaning of [HCO<sub>3</sub>], even though the recitation does not include a charge. Accordingly, contrary to the Examiner's assertions, the subject matter embraced by claims 3-11 is clear and definite".

In response, it is immaterial that claim 1 of patent '486 has been found allowable. Claims do not recite the charge for bicarbonate anion and where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so



as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “[HCO<sub>3</sub>]” in claims 3-11 is used by the claim to mean anion”, while the accepted meaning is “[HCO<sub>3</sub>]-.” The term is indefinite because the specification does not clearly redefine the term.

Applicants’ also argue:

“Further, the Examiner asserts that the expression "derivatives thereof (at all occurrences) is without metes and bounds." *Id.* Applicants respectfully disagree with the Examiner's assertion. Breadth of a claim is not to be equated with indefiniteness and this is not an appropriate test for definiteness under the second paragraph of the statute. See *id.* at § 2173.04. If the scope of the subject matter is clear, and if Applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph. *Id.* Stated another way, the test of definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Definiteness of claim language should be analyzed in light of: (A) the content of the particular disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. M.P.E.P. § 2173.02. The meaning of the term "derivative" is well-known to one of ordinary skill in the art. Further, claim 19 is not without metes and bounds because the dye precursors recited in claim 19,

including the "derivatives thereof," are species within the parameters of the structural genus recited in claim 1. Therefore, despite the Examiner's contentions, the scope of the subject matter embraced by the claims is clear and definite".

In response, specification does not define the scope of "species" under derivatives and the meaning of "derivative" may be well known to one of ordinary skill in the art but due to lack of scope of definition for "derivatives thereof", a person of ordinary skill in the art could not interpret the metes and bound of claims so as to understand on how to avoid infringement (emphasis added).

#### *Claim Rejections - 35 USC § 103*

In view of common ownership statement, the rejection of claims 1-41, 50-53, 66 and 68-69 are rejected under 35 U.S.C. 103(a) as being obvious over the combination of U. S. Patents 6,953,486 ('486) and 6,736,861('861) is hereby withdrawn.

Claims 1-41, 50-53, 66 and 68-69 are rejected under 35 U.S.C. 103(a) as being obvious over the combination of WO 02/30375 ('375) and 6,736,861('861).

U. S. Patent 6,953,486 is the English equivalent for WO 02/30375. Examiner is relying on the disclosure of the patent.

Patent '486 teaches dyeing compositions also known as coloring compositions for coloring the keratin (skin or hair). See the abstract. Patent '486 teaches coloring using dye precursor at col.3, line 56 to col.4, line 25 and the claimed catalytic system at col.2, line 51 to col.col.3, line 55. Patent at col.5, ll 36-48 teaches plant extracts claimed in claims 20-21. Patent at col.6, ll 53-68 teaches physiologically acceptable medium claimed in claims 25-28 and teaches

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the weight percent at col.7, ll 7-11 (claims 29-31). Patent at col.8, ll 23-42 teaches that the composition can be packed in two discrete containers or it can be packed in a single compartment. See the examples and see also claims. The difference between the WO document and instant application is WO document does not teach composition also having an acidic composition or basic composition. However, patent '861 teaches color hair using acidic composition and basic composition. See claim 1 and see col.3, line 10 through col.4, line 41.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare hair coloring compositions of WO document and add to the compositions an acidic composition and basic composition of patent '881. It is prima facie obvious to combine two compositions which have been used individually for the same purpose since the idea of combining the ingredients flows logically from the art.

### ***Response to Arguments***

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

Applicants' argue:

“Patel discloses a daily hair care composition comprising a mixture of two compositions, part A and part B. See Patel at col. 3, lines 10-11. According to Patel, Part A is dye intermediates in a conditioner or shampoo base at alkaline pH and Part B is hydrogen peroxide in a conditioner or shampoo base at acidic pH. Id. at col. 3, lines 12-15 (emphasis added). As discussed above, the Examiner asserts that it would have been obvious to add the hair care composition of Patel comprising a mixture of an acidic composition and a basic composition to the hair

coloring compositions disclosed in Pruche to arrive at Applicants' claimed invention. See Office Action, at page 10. However, in Applicants' view, Pruche actually teaches away from such a combination. The coloring compositions disclosed in Pruche "have the advantage of not requiring the use of hydrogen peroxide." Pruche at col. 8, lines 19-20 (emphasis added). One of ordinary skill would not have a reason to include the composition disclosed in Patel, comprising two components, one of which contains hydrogen peroxide, in the coloring compositions as disclosed by Pruche. Prior art must be considered in its entirety, including disclosures that teach away from the claims. M.P.E.P. §§ 2141.02(VI). Indeed, the Federal Circuit has repeatedly recognized that proceeding contrary to the accepted wisdom in the art represents "strong evidence of unobviousness." *In re Hedges*, 783 F.2d 1038, 1041, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986). Thus, the predominantly negative (i.e., regarding use of hydrogen peroxide) disclosure of Pruche cannot justifiably be considered support for a prima facie case of obviousness".

In response to prior art teaching away "using hydrogen peroxide" and secondary reference teaching compositions with hydrogen peroxide, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Patent '486 teaches a coloring composition for keratin materials using component (i) and patent '861 teaches coloring of hair (coloring composition for keratin materials) using component s (ii) and (iii) and one of ordinary skill in the hair care art would prepare a third composition for coloring keratin materials by combining components (i) of patent '486 and components (ii) and (iii) of patent '861 and use the third composition for coloring keratin materials. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art.

Additionally, the use of the term " comprising" is inclusive of " hydrogen peroxide" since the term " comprising" permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. Moleculon Research corp., v. CBS, Inc., 793 F. 2d 1261, 229 USPQ 805 (FED. Cir. 1986); In re Baxter, 656 F. 2d 679, 210 USPQ 795, 803 (CCPA 1981).

### ***Double Patenting***

Claims 1-41, 50-53, 66 and 68-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,953,486 in view of 6,736,861 ('861). The instant application and the patent are claiming compositions using the same dyeing precursor and also catalytic system. Patent does not claim compositions having acidic composition and basic composition. See the explanation under 103.

***Response to Arguments***

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

Applicants' argue:

"Prior art must be considered in its entirety, including disclosures that teach away from the claims. M.P.E.P. §§ 2141.02(VI). As discussed above, Pruche teaches away from including a hydrogen peroxide component, as required by Patel, in a coloring composition. Accordingly, for at least the reasons discussed above, the claimed invention would not have been prima facie obvious over the combination of Pruche and Patel".

In response, to prior art teaching away "using hydrogen peroxide" and secondary reference teaching compositions with hydrogen peroxide, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Patent '486 claims a coloring composition for keratin materials using component (i) and patent '861 teaches coloring of hair (coloring composition for keratin materials) using component s (ii) and (iii) and one of ordinary skill in the hair care art would prepare a third composition for coloring keratin materials by combining components (i) of patent '486 and components (ii) and (iii) of patent '861 and use the third composition for coloring keratin materials and it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for

the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art.

This application contains claims 58-65 and 67 drawn to an invention nonelected with traverse in the reply filed on 9/7/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /

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Primary Examiner, Art Unit 1615